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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 08/970,045      | 11/13/1997  | EUGEN KOREN          | 20487/113           | 2118             |

7590 10/02/2002

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EXAMINER

DUFFY, PATRICIA ANN

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1645

DATE MAILED: 10/02/2002

29

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.  
**08/970,045**

Applicant(s)  
**Koren et al**

Examiner  
**Patricia A. Duffy**

Art Unit  
**1645**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Apr 22, 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-13 and 39-47 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-11, 39, 41-43, 46, and 47 is/are allowed.
- 6) ☒ Claim(s) 12, 13, 40, 44, and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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***Response to Amendment***

1. The amendment filed April 22, 2002 has been entered into the record. Claims 1-13 and 39-47 are pending.
2. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action. Any rejections not specifically reiterated herein are withdrawn.

***Rejections Withdrawn***

3. The rejection of claim 39 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn in view of Applicants' arguments.
4. The rejection of claims 42-45 under 35 U.S.C. 103(a) as being unpatentable over Koren et al (Atherosclerosis, 95:157-170, 1992) is withdrawn in view of Applicants' amendments.
5. The rejection of claims 1, 10 and 11 under 35 U.S.C. 103(a) as being unpatentable over Fish et al (U.S. Patent No. 5,126,276, published June 30, 1992), Scripps Clinic and Research Foundation (EP 0 262 854, published April 6, 1988), Forster et al (Biochem. Soc. Trans. 18(6):1180, December 1990), Zhou et al (Hubei Yixueyuan Xuebao., Vol II, No.4, pp. 298-302, 1990) in view of Koren et al

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(Atherosclerosis, 95:157-170, 1992) is withdrawn in view of Applicants' amendments that both antibodies bind lipoproteins with the argued specificity.

6. The rejection of claim 6 under 35 U.S.C. 103(a) as being unpatentable over Fish et al (U.S. Patent No. 5,126,276, published June 30, 1992), Scripps Clinic and Research Foundation (EP 0 262 854, published April 6, 1988), Forster et al (Biochem. Soc. Trans. 18(6):1180, December 1990), Zhou et al (Hubi Yixueyuan Xuebo., Vol II, No.4, pp. 298-302, 1990) and Koren et al (Atherosclerosis, 95:157-170, 1992) as applied to claims 1, 10 and 11 above, and further in view of Luca (EP 0 407 035, published 2/3/88) is withdrawn in view of Applicants' amendments that both antibodies bind lipoproteins with the argued specificity.

7. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fish et al (U.S. Patent No. 5,126,276, published June 30, 1992), Scripps Clinic and Research Foundation (EP 0 262 854, published April 6, 1988), Forster et al (Biochem. Soc. Trans. 18(6):1180, December 1990), Zhou et al (Hubi Yixueyuan Xuebo., Vol II, No.4, pp. 298-302, 1990), Koren et al (Atherosclerosis, 95:157-170, 1992) and Luca (EP 0 407 035, published 2/3/88) and as applied to claim 6 above, and further in view of Mills et al (Laboratory Techniques in biochemistry and molecular biology, Volume 14, A Guidebook to Lipoprotein Technique; 1984, pages 472-478) is withdrawn in view of Applicants' amendments that both antibodies bind lipoproteins with the argued specificity.

8. Claims 12 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fish et al (U.S. Patent No. 5,126,276, published June 30, 1992), Scripps Clinic

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and Research Foundation (EP 0 262 854, published April 6, 1988), Forster et al (Biochem. Soc. Trans. 18(6):1180, December 1990), Zhou et al (Hubei Yixueyuan Xuebao., Vol II, No.4, pp. 298-302, 1990) and Koren et al (Atherosclerosis, 95:157-170, 1992) as applied to claims 1, 10, and 11 above, and further in view of Scripps Clinic (EP 0 257 778, published 2/3/88) is withdrawn in view of Applicants' amendments that both antibodies bind lipoproteins with the argued specificity.

9. Claims 1, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fish et al (U.S. Patent No. 5,126,276, published June 30, 1992), Scripps Clinic and Research Foundation (EP 0 262 854, published April 6, 1988), Forster et al (Biochem. Soc. Trans. 18(6):1180, December 1990), Zhou et al (Hubei Yixueyuan Xuebao., Vol II, No.4, pp. 298-302, 1990) and Koren et al (Atherosclerosis, 95:157-170, 1992) as applied to claims 1, 10 and 11 above, and further in view of Curtiss et al (U.S. Patent 4,677,057, published June 30, 1987) is withdrawn in view of Applicants' amendments that both antibodies bind lipoproteins with the argued specificity.

### ***Rejections Maintained***

10. Claims 12-13, 40, 44 and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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As to claim 12 and dependent claim 13, the claim still fails to determine the concentration of at least two different apolipoproteins in a biological sample as set forth in the preamble. The method steps only achieve the determination of the apolipoprotein bound to *either the first or second monoclonal antibody* and the third immobilized monoclonal antibodies. As such, the goal of the preamble does not match the method steps and final outcome of the assay.

As to claim 40, the amendment to recite "... separating the complexed anti-ApoC-III antibody ApoC-III containing lipoprotein particles from the biological sample.." renders the claim unclear because now, it is unclear which how determining the amount of apoC-III present in HDL in the anti-Apo C-III-anti Apo A-I complexed material in the sample" is achieved. The complex that is should be separated is the anti-Apo C-III-anti Apo A-I complexed material, otherwise the assay does not achieve the goal of the method steps (see step (b) lines 12-13 therein). Applicants' amendments do not obviate this rejection. Correction is required.

As to claims 44 and 45, the term "predominantly" is a relative term which renders the claim indefinite. Applicants' arguments have been carefully considered but are not persuasive. The term predominantly as conventionally defined references absolute numbers whereas herein it is used to relate binding specificity which is a relative term, not absolute numbers. The number antibodies present does not determine the degree of specificity and as such the conventional definition based on a predominant number does not specifically translate any

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"degree of specificity" as it is used in the claims because specificity is not governed by absolute number but by the association/dissociation constant of the antibody relative to a second antibody. As such, Applicants reliance on the common meaning of the term with respect to dominance of absolute numbers is not persuasive.

***New Rejections Based on Amendment***

11. Claims 12 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants have amended the base claim 12 to recite, "....subtracting from the total apolipoprotein bound....apolipoproteins". However, this recitation apparently fails to have written description support in the specification as filed. This issue is best resolved by Applicants' pointing to the specification by page and line number where support for the amendment can be found.

12. Claims 12 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

As to claims 12 and 13, the recitation of "... subtracting the total apolipoprotein bound by the first and second antibodies..." has no antecedent basis

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in the claims. Further, there is no determining step that allows the determination of the individual apolipoproteins. As such, the method is unclear.

### *Status of Claims*

13. Claims 12, 13, 40, 44 and 45 stand rejected. Claims 1-11, 39, 41-43 and 46 and 47 are allowed.

### *Conclusion*

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.



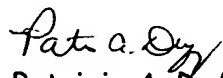
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15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia A. Duffy, Ph.D. whose telephone number is (703) 305-7555. The examiner can normally be reached on Monday-Thursday and Saturday from 10:30 AM to 7:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached at (703) 308-3909.

Patricia A. Duffy, Ph.D.  
October 1, 2002

  
Patricia A. Duffy, Ph.D.  
Primary Examiner  
Group 1600